and provide for the performance and assessment of work.

Reactor means, unless it is modified by words such as containment, vessel, or core, the entire nuclear reactor facility, including the housing, equipment, and associated areas devoted to the operation and maintenance of one or more reactor cores. Any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner, including critical and pulsed assemblies and research, test, and power reactors, is defined as a reactor. All assemblies designed to perform subcritical experiments that could potentially reach criticality are also to be considered reactors. Critical assemblies are special nuclear devices designed and used to sustain nuclear reactions. Critical assemblies may be subject to frequent core and lattice configuration change and may be used frequently as mockups of reactor configurations.

Record means a completed document or other media that provides objective evidence of an item, service, or process.

Service means the performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

(b) Terms defined in the Act and not defined in these rules are used consistent with the meanings given in the Act.

(c) As used in this part, words in the singular also include the plural and words in the masculine gender also include the feminine and vice versa, as the case may require.

§ 830.4 General rule.

(a) No person shall take or cause to be taken any action inconsistent with the requirements of this part or any program, plan, schedule, or other process established by this part.

(b) With respect to a particular DOE nuclear facility, the contractor responsible for the design, construction, operation, or decommissioning of that facility shall be responsible for implementation of, and compliance with, the requirements of this part.

(c) When a section of this part expressly requires a plan, program, or implementation plan, the provisions of any such plan, program, or implementation plan, as approved by DOE, shall be the basis used to determine compliance with the relevant nuclear safety requirements in the section.

§ 830.5 Enforcement.

The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of part 820 of this title.

§ 830.6 Records.

A person shall maintain complete and accurate records as necessary to substantiate its compliance with the requirements of this part.

§ 830.7 Graded approach.

(a) Where indicated in a subpart, a graded approach shall be utilized to comply with the requirements.

(b) Whenever a graded approach is applied in meeting a DOE nuclear safety requirement, the bases for selecting an action pursuant to the graded approach shall be documented.

Subpart A—General Provisions

§ 830.100 Scope of subpart.

This subpart prescribes requirements that are generally applicable to more than one phase of the life cycle of a DOE nuclear facility.

§ 830.120 Quality assurance requirements.

(a) *General Rule.* (1) A contractor responsible for a DOE nuclear facility shall:

(i) Conduct its work in accordance with the criteria of paragraph (c) of this section;

(ii) Develop and submit for approval by DOE a Quality Assurance Program (QAP) for the work; and

(iii) Implement the QAP, as approved and modified by DOE.

(b) *Quality Assurance Program.* (1) A contractor shall develop a QAP by applying the quality assurance criteria specified in paragraph (c) of this section. A QAP shall include a discussion of how the criteria of paragraph (c) of

this section will be satisfied. The criteria of paragraph (c) of this section shall be applied using a graded approach. The contractor shall use appropriate standards, wherever applicable, to develop and implement its QAP.

(2) Within 180 days after May 5, 1994, a contractor shall submit to DOE for approval a current QAP and an implementation plan.

(3) A contractor may, at any time, make changes to an approved QAP. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this section. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.

(4) Implementation plans and QAPs shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and shall include any modification made or directed by DOE.

(c) *Quality assurance criteria.*—(1) *Management* (i) *Program.* A written QAP shall be developed, implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe management processes, including planning, scheduling, and resource considerations.

(ii) *Personnel Training and Qualification.* Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.

(iii) *Quality Improvement.* Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement.

(iv) *Documents and Records.* Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

(2) *Performance*—(i) *Work Processes.* Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

(ii) *Design.* Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.

(iii) *Procurement.* Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.

(iv) *Inspection and Acceptance Testing.* Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

(3) *Assessment*—(i) *Management Assessment.* Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

(ii) *Independent Assessment.* Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

Subpart B—Design [Reserved]

Subpart C—Operations [Reserved]

Subpart D—Material Management [Reserved]

PART 835—OCCUPATIONAL RADIATION PROTECTION

Subpart A—General Provisions

Sec.

Subpart B—Management and Administrative Requirements

Subpart C—Standards for Internal and External Exposure

Subpart D [Reserved]

Subpart E—Monitoring of Individuals and Areas

Subpart F—Entry Control Program

Subpart G—Posting and Labeling

Subpart H—Records

Subpart I—Reports to Individuals

Subpart J—Radiation Safety Training

Subpart K—Design and Control

Subpart L—Radioactive Contamination Control

Subpart M—Sealed Radioactive Source Control

Subpart N—Emergency Exposure Situations